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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,298	04/07/2004	John Sefton	17224CON (AP)	7456

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EXAMINER

BADIO, BARBARA P

ART UNIT PAPER NUMBER

1617

DATE MAILED: 05/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/820,298

Applicant(s)

SEFTON, JOHN

Examiner

Barbara P. Badio, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

NP

Final Office Action on the Merits

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Double Patenting

2. The provisional rejection of claims 1-11 under the judicially created doctrine of obviousness-type double patenting over claims of copending Application No. 09/367,712 is maintained.

The examiner notes applicant's lack of response to the above rejection.

Claim Rejections - 35 USC § 112

3. The rejection of claims 4 and 9 under 35 USC 112, second paragraph is withdrawn.

Claim Rejections - 35 USC § 103

4. The rejection of claims 1-11 under 35 USC 103(a) over Yamamoto ('906) and Nagpal et al. ('279) in combination is maintained.

Applicant's argues unexpected result is supported by the affidavit and remarks filed February 8, 2005. Applicant argues there is a trend of reduction in adverse events with the combination of tazarotene and corticosteroid as the potency of said

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corticosteroid is increased. Applicant's argument was considered but not persuasive for the following reasons.

First, the examiner disagrees that "it is generally unexpected that a treatment would increase efficacy while reducing adverse effects". The examiner assumes by "treatment" applicant means combination therapy. The general expectation with combination therapy is a reduction in adverse effect due to individual drugs with the utilization of combination therapy. Applicant also argues that one would generally expect that the administration of combination therapy when one of the active agents is given in the same dose for individual and combination therapy would result in increase in adverse effects. The examiner also disagrees since the adverse effect of the active ingredients might be different. If the active agents individually result in different adverse reaction(s), the skilled artisan would not expect the combination to result in increase in adverse effect due to a single active agent.

Secondly, the evidence of record does not support applicant's assertion that there is a trend or reduction in adverse events with the combination of tazarotene and corticosteroid as the potency of said corticosteroid is increased, i.e., unexpected results. The data presented in Table II of the present specification shows increase in burning in the taz/high group versus the other groups including the taz/plac group. It also shows an increase or no change in irritation in the taz/low versus the taz/plac group; similar incidence of erythema in all three groups given corticosteroid; and an increase incidence of pruritus in taz/low group versus taz/plac group and an increase or no change in taz/med group versus taz/plac.

Applicant also argues the data presented in Gollnick supports the general trend of a reduction in adverse events with the combination of tazarotene and corticosteroids compared to tazarotene alone. As stated in the previous Office Action, the data shows no difference with the utilization of med- versus high-potency corticosteroid and, thus, does not support applicant's assertion of a trend towards a decrease in adverse effect with increase in the potency of corticosteroid.

In addition, like the data presented in the present specification, the comparison is with different doses of corticosteroids. Based on the utilization of low-, med- and high-potency, the skilled artisan would have the reasonable expectation that the effective amount of each group of corticosteroid would decrease accordingly and thus, comparison would be based on decreasing doses of corticosteroid with increase potency. However, it is noted that the amount of high-potency corticosteroid is twice the amount of med-potency corticosteroid in the present specification or four times the amount of low-potency corticosteroid in the Gollnick reference.

In summary, (a) a reduction in adverse effect with combination therapy is not unobvious or unexpected and (b) the data presented by applicant does not support said argument of unexpected results as discussed above.

For these reasons and those given in previous Office Action, the rejection of claims 1-11 under 35 USC 103(a) over Yamamoto ('906) and Nagpal et al. ('279) in combination is maintained.

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5. The rejection of claims 1-11 under 35 USC 103(a) over Smith ('074) or Sequeira et al. ('529) and Nagpal et al. ('279) in combination is maintained.

See discussion given above in #4.

Conclusion

6. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Telephone Inquiry


7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax

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phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1617

BB
May 17, 2005